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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,837

04/17/2006

Tomoko Hongo

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466 7590 11/25/2008

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EXAMINER

WANG, CHUN CHENG

ART UNIT

PAPER NUMBER

1796

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DELIVERY MODE

11/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/564,837	HONGO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Chun-Cheng Wang	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 34-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/17/2006, 04/11/2006 and 07/22/2008</u> .                   | 6) <input type="checkbox"/> Other: _____                          |



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## **DETAILED ACTION**

### ***Priority***

Claims 34-63 are pending.

1. Acknowledgment is made of applicant's claim for foreign priority under 35

U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. JP2003-422496 and JP2003-275847, filed on 01/17/2006.

### ***Claim Objections***

2. Claims 42, 46 and 55 are objected to because of the following informalities: Claims contain "cellulose-type" term.
3. Claim 48 is objected to because of the following informalities: Claim 48 refers to nonexistent claim 14.
4. Claims 36-37, 40 and 45 are objected to because of the following informalities: Change "characterized in that" to "wherein".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 48 recites "The adsorption preventive method according to claim 14", while claim 14 is canceled.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 34-47 and 49-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Katsuhiro et al. (JP 2002-180110).

Katsuhiro et al. disclose a manufacturing method of metallic colloidal solution that can be easily carried out by control of particle diameter, while obtain a stable metallic colloidal solution ([0006]). Mono dispersion of the metallic colloid particles diameters are in the range whose mean particle diameter is 3-200 nm (read on claims 34-37, 40-41 and 45). The metallic colloid particle has narrow particle size distribution,  $\pm 20\%$  of mean particle diameter contribute greater than 80% of the weight ([0032]). Dispersant such as polyvinylpyrrolidone (read on claims 51) was used in the metallic colloidal solution ([0012]). Water, alcohols and ketones can be used as solvent ([0016]). Organic acid such as polycarboxylic acid can be used as a stabilizer, i.e. chelating agent ([0012]). Metals from the group of Au, Ag, Cu, nickel, Co, Fe, Pd and Ru can be used to manufacture the solution ([0008]). Surfactant like sodium dodecyl benzenesulfonate and sodium laurate may be used ([0012]). Reducing agent, such as hypophosphite, sodium borohydride, alcohols, hydrazine, formaldehyde and dimethylamine borane, may be used alone

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or together ([0025]). The metal colloid particles can be obtained by using ultrafiltration to separate particles precipitate and solution ([0029]). An extremely stable metallic colloidal solution can be obtained. The particle diameter of the metallic colloid particles is also uniform ([0033]).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuhiro et al. (JP 2002-180110) in view of Meltzer et al. ("Filtration in the Pharmaceutical Industry", Marcel Dekker, New York, 1998, page 548-559 and 636-637).

The disclosure of Katsuhiro et al. is adequately set forth above and is incorporated herein by reference.

Katsuhiro et al. is silent on the membrane material.

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Meltzer et al. disclose protein adsorption test on cellulose acetate (page 551, line 1), modified polyethersulfone and modified polyvinylidene fluoride (PVDF) (page 554, line 12) membranes for filtration. Both modified polyethersulfone and modified PVDF show extremely low protein adsorption, i.e. less protein loss due to filtration (page 554, lines 16-17).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to use low protein adsorption membranes for virus removal ultrafiltration.

12. Claims 54 and 56-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meltzer et al. ("Filtration in the Pharmaceutical Industry", Marcel Dekker, New York, 1998, page 548-559 and 636-637) in view of Katsuhiro et al. (JP 2002-180110).

Meltzer et al. disclose the integrity of virus removal membranes is measured by a particle challenge test using dextran, PVP or colloidal gold. The ability of the membrane sample to retain either larger or smaller virus particles can be approximated by varying the particle size within the challenge solution (5.1 Integrity Testing, page 636). Meltzer et al. also disclose protein adsorption test on cellulose acetate (page 551, line 1), modified polyethersulfone and modified polyvinylidene fluoride (PVDF) (page 554, line 12) membranes for filtration. Both modified polyethersulfone and modified PVDF show extremely low protein adsorption (page 554, lines 16-17).

Meltzer et al. is silent on the components of the gold colloid solution.

Katsuhiro et al. disclose metallic colloidal solution that can be easily manufactured by control of particle diameter to obtain a stable metallic colloidal solution ([0006]). The mono dispersion metallic colloid particles have mean diameters of 3-200 nm and narrow particle size

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distribution,  $\pm 20\%$  of mean particle diameter contribute greater than 80% of the weight ([0032]).

Dispersant such as polyvinylpyrrolidone was used in the metallic colloidal solution ([0012]).

Water, alcohols and ketones can be used as solvent ([0016]). Organic acid such as

polycarboxylic acid can be used as a stabilizer, i.e. chelating agent ([0012]). Metals from the

group of Au, Ag, Cu, Ni, Co, Fe, Pd and Ru can be used to manufacture the colloidal solution

([0008]). The metallic colloid particles offer the advantages of stability and monodispersion, i.e.

narrower particle size distribution for more accurate test.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to utilize the advantages of uniform particle sizes and stability of the colloid solution to perform the integrity test.

13. Claims 55 and 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tateishi et al. ("Scrapie Removal using Planova Removal Filters", Biological (2001) 29, page 17-25) in view of Naoki et al. (JP 2002-060805).

Takeishi et al. disclose Small-sized Planova filters comprised of a cuprammonium regenerated cellulose membrane in mean pore sizes of  $35 \pm 2$  nm (Planova 35N),  $15 \pm 2$  nm (Planova 15N) and  $9 \pm 2$  nm (Planova 10N) were evaluated. Gold particle removability tests after filtration were performed to verify the membrane integrity of each filter used (Filtration, page 18).

Takeishi et al. is silent on the metal colloid composition, dodecylsulfuric acid and chelating agent.

Naoki et al. disclose multi-component metallic colloidal solution that can be easily manufactured ([0001]). The metallic colloid particles have mean diameters of  $\leq 100$  nm ([0015]).



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Protecting agent such as polyvinylpyrrolidone was used in the metallic colloidal solution ([0020]). Water, alcohols and ether can be used as solvent ([0016]). Organic molecules with carboxylic acid, read on polyacrylic acid, can be used as a chelating agent ([0023]). Sodium dodecyl sulfate can be used as surfactant ([0024]). Metals from the group of Au, Ag, Cu, Rh, Os, Ir, Pt, Pd and Ru can be used to manufacture the colloidal solution ([0013]). The manufacturing method offers a convenient way to prepare multi-component metal colloid solution.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to utilize the convenient method to prepare multi-component metal colloid solution for the integrity test.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun-Cheng Wang whose telephone number is (571)270-5459. The examiner can normally be reached on Monday to Friday w/alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ling-Siu Choi/  
Primary Examiner, Art Unit 1796

Chun-Cheng Wang  
Examiner  
Art Unit 1796

/CCW/